



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

November 19, 2004

FILE COPY

Christopher V. Powala
Vice President, Drug Development and Regulatory Affairs
CollaGenex Pharmaceuticals, Inc.
41 University Drive
Newtown, PA 18940

Dear Mr. Powala:

Your petition requesting the Food and Drug Administration to stay approval of any ANDAs submitted by Ivax Pharmaceuticals, Inc., CorePharma LLC or any other party for which CollaGenex's Periostat (doxycycline hyclate 20mg) is the reference listed drug unless that ANDA's bioequivalence study or studies include female subjects, was received by this office on 11/19/2004. It was assigned docket number 2004P-0517/PSA 1 and it was filed on 11/19/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

cc: Nancy L. Buc
Carolyn L. Hann
Buc & Beardsley
919 Eighteenth Street, N.W.
Suite 600
Washington, DC 20006

2004P-0517

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